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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,339	11/09/2000	Henrik Bisgard-Frantzen	5835.200-US	9183

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/710,339

Applicant(s)
Bisgard-Frantzen et al.

Examiner
Maryam Monshipouri

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-33 and 39-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-33 and 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 19 6) ☐ Other:

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Claims 1-30, 34-38, 44-47 and 49 have been canceled. Claims 31-33, 39-43 and 48 are at issue and are present for examination.

Applicants' arguments filed on 1/06/2003 (paper # 18), have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The substitute sequence listing filed 1/23/2003 is confusing. It is not clear why the total number of sequences have been increased to 6 relative to originally filed sequence listing. Also, it is unclear as to why SEQ ID NO:3 which originally was a DNA sequence is changed to an amino acid sequence. Further, the difference between SEQ ID NO:2-3 is not indicated in comments. Clarification and appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 32 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It appears that applicant replaced the original SEQ ID NO:2 with a substitute wherein Q132 is occupied by a glutamine in substitute sequence listing. However, due to unclarity

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of the substitute sequence listing (see above) with respect to SEQ ID NO:2-3, the rejection could not be withdrawn.

3. *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 31-33, 39-43 and 48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Christianson (cited previously), in view of Matsuura (cited previously) further in view of Svendsen (cited previously), as stated previously. In traversal of this rejection applicant argues the following: (1) that none of the references alone teach the variants of this invention and (2) that the cited art only teaches about bacterial amylase variants and not the fungal amylase variants and despite examiner's contention Svendsen alterations are based on the aspects of bacterial related alpha-amylases which have very low homology and extremely low identity to the fungal related alpha-amylases of the present invention. Applicant then cites page 3, lines 6-18 of Svendsen stating that the variants it describes are "based on some striking, and not previously predicted difference between" the Termamyl-like alpha-amylase structure and both fungal and mammalian alpha amylase.

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Thus, according to applicant Svendsen alone or in combination with Christianson and Matsuura clearly does not suggest the alterations in fungal related alpha amylases and therefore the rejection should be withdrawn.

These arguments were fully considered but was found **unpersuasive** for the following reasons: with respect to applicant's **first** argument the examiner would like to indicate that had any of the cited art alone, taught the variants of this invention said art would have been anticipatory to this invention.

In response to applicant's **second** argument the examiner agrees with the applicant that the cited art teaches about variants of bacterial amylase variants and bacterial related amylases have relatively low sequence homology to fungal related amylases and Svendsen exploited regions of low homology to fungal amylases for variant preparation. Nevertheless, the examiner maintains that based on the ample knowledge of various domains of conserved/non-conserved homology of amylases in the prior art, to one of ordinary skill in the art, preparation of variants of any amylase with predicted properties, is obvious and does not require undue experimentation.

This conclusion is particularly supported by the fact that structural characterization of amylases in the prior art are not merely based on amino acid homology (identity) but also based on physical properties of constituent amino acids of said enzymes. Applicant is respectfully requested to consider Holm et al. (Protein Engineering, 3(3), 181-191, 1990, attached) which aligns various amylases from fungal (Taka- amylase), mammalian and bacterial sources using physical properties of constituent amino acids as a basis for alignment and points out domains A

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and C (see figure 1) of high structural similarity around the catalytic site and secondary structure elements, as well as domains of very little amino acid homology or similarity in beta strand arrangement (domain b), to be exploited for variant preparation with predicted activities.

Furthermore, Holm indicates that the three dimensional model of *B. Stearothermophilis* (bacterial) alpha amylase (like many other amylases in the prior art) is based on, or modeled after, Taka-amylase (fungal source) whose three dimensional structure was the first characterized in the prior art. Said fact about Taka amylases is also indicated in Svendsen (see page 2).

Thus, in summary, the criteria for aligning the structures of various amylases is not merely amino acid homology (identity) but others such as physical properties of constituent amino acids (see Holm et al., above), mostly based on/modeled after the three dimensional structure of fungal amylases, which lead to amylase variant preparations and products with predicted properties from any source or species, such as those of this invention. Details of such methods and products thereof in the case of fungamyl-like alpha amylase variants of this invention have been already elaborated in the previous 103 rejection.

Hence, the examiner maintains that the combined teachings of Christianson in view of Matsuura further in view of Svendsen continue to render the claimed invention obvious and to artisan of ordinary skill, at first glance, using mutated residues of Svendsen with retained activity, as a guide to obtain fungamyl-like amylase variants of this invention (see previous office action) is reasonably expected to result in successful preparation of claimed variants.

No claims are allowed.

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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.


Maryam Monshipouri, Ph.D.

Primary Examiner